



## Evaluation of performance of orient gene strep a rapid antigen test in tonsillopharyngitis

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### Abstract

**Aim:** The aim of this study is to investigate the performance of Orient Gene Strep A rapid test kit (Zhuhai Encode Medical, China), which detects the presence of Lancefield Group A antigen of *S. pyogenes* in throat swab specimens by lateral flow immunoassay, in comparison with throat culture. **Material and Method:** A total of 250 throat swabs obtained from pediatric patients who were admitted to Akdeniz University Hospital between January 20, 2015 and March 4, 2016 for acute tonsillopharyngitis were included in the study. Throat swab specimens were placed on the transport medium (Copan, Italy) and plated on Columbia blood agar plates (BBL, BD, US). Plates were incubated for 24-48 hours at 35-37 °C under aerobic conditions. *S. pyogenes* isolates were identified by colony morphology, beta hemolysis formation, L-pyrrolidonyl-naphthylamide (PYR, Remel, USA) hydrolysis, Lancefield group typing kit (Plasmatec, UK) and MALDI-TOF MS (Bruker Daltonik, GmbH, Germany). **Results:** *S. pyogenes* growth was observed in 54 (21.6%) of the 250 samples that were being worked on. Rapid antigen test was positive in 46 (85.2%) of those 54 culture positive cases and negative in the remaining 8 (14.8%) cases. Moreover, strep-A rapid diagnostic test was positive in 4 cases with negative culture. The sensitivity and specificity of Orient Gene Strep A compared with culture were 85.2% and 98%, respectively. **Discussion:** Orient Gene Strep A rapid test is inexpensive and provides rapid results with considerable sensitivity and specificity so is suitable for using together with culture for the diagnosis of streptococcal pharyngitis.

### Keywords

Streptococcus Pyogenes; Throat Culture; Orient Gene Strep A Rapid Test

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Introduction

*S. pyogenes* emerges as a causative agent in approximately 616 million pharyngitis cases per year [1]. Suppurative complications such as peritonsillar abscess, retropharyngeal abscess, cervical adenitis, otitis media, sinusitis, mastoiditis, bacteremia and nonsuppurative complications such as acute rheumatic fever and acute glomerulonephritis may develop due to pharyngitis caused by *S. pyogenes* [2]. At least 517,000 people die each year due to serious *S. pyogenes* infections worldwide, and acute rheumatic fever alone accounts for 233,000 of these cases [3]. Untreated streptococcal pharyngitis lasts 7-10 days. Patients with untreated streptococcal pharyngitis are infectious during the acute phase of the disease and for the next week. Effective antibiotic treatment reduces the risk of transmission and symptom duration to about one day. Appropriate treatment of GAS pharyngitis also prevents most complications [4]. On the other hand, inappropriate use of antibiotics contributes to antimicrobial resistance development, side effects and excess health care costs [2,5].

Clinical findings may provide insight into the causative agent, but it is not always possible even for experienced physicians to make a definite decision as to whether the agent is *S. pyogenes*. In the diagnosis of acute tonsillopharyngitis due to *S. pyogenes*, culture method, rapid antigen tests, polymerase chain reaction (PCR) and serological tests are used. Culture is the gold standard method [6]. The sensitivity of the culture method is 90-95% when the throat sample is collected, transported, incubated and evaluated properly [2]. However, the culture method takes 1-2 days to get results (and it requires more experience and laboratory equipment). Serological tests can be used to diagnose non-suppurative complications, but they are not useful in diagnosing acute infection because antibody titers reach detectable levels after 1-2 weeks of acute infection, reaching a maximum level within 3-6 weeks after acute infection, and after months of infection, it may still be high even if it is not active streptococcal pharyngitis [7]. Tests for detecting nucleic acids are highly sensitive but they are very costly.

Rapid antigen tests detect the carbohydrate antigen presence in the cell wall of *S. pyogenes*. These tests are simple to perform. There are many commercial kits available for rapid antigen test. In this test, first, the antigen is extracted from the sample of the throat swab by enzymatic or chemical methods. After that, antigen presence is demonstrated by methods such as enzyme immunoassay (EIA) and agglutination [8].

According to the recommendations of IDSA, testing for GAS pharyngitis by rapid antigen testing and/or culture should be performed if the patient has no cough, nasal discharge, oral ulcer or hoarseness [4]. These symptoms strongly suggest viral etiology. A streptococcal pharyngitis cannot reliably be distinguished from viral pharyngitis according to clinical findings. In pediatric patients, confirmation with culture is recommended if the rapid antigen test is negative. If the result of the rapid antigen test is positive, culture is not necessary because the test has high specificity.

ESCMID recommends the use of Centor clinical scoring system or rapid antigen test for the diagnosis of group A streptococcal sore throat. According to the Centor criteria (temperature > 38°C, absence of cough, tonsillar exudates, tender anterior cer-

vical adenopathy) in patients with a high probability of group A streptococcal infection, rapid antigen testing can be performed. If the rapid antigen test result is negative, then the culture is not necessary [9,10].

In this study, our aim is to investigate the performance of Orient Gene Strep A rapid test kit (Zhuhai Encode Medical, China), which detects the presence of Lancefield Group A antigen of *S. pyogenes* in throat swab specimens by lateral flow immunoassay, in comparison with throat culture.

**Material and Method**

A total of 250 throat swabs obtained from pediatric patients who were admitted to Akdeniz University Hospital between January 20, 2015 and March 4, 2016 for acute tonsillopharyngitis were included in the study. Throat swab specimens were placed on the transport medium (Copan, Italy) and plated on Columbia blood agar plates (BBL, BD, US). Plates were incubated for 24-48 hours at 35-37 °C under aerobic conditions. *S. pyogenes* isolates were identified by colony morphology, beta hemolysis formation, L-pyrrolidonyl-naphthylamide (PYR, Remel, USA) hydrolysis, Lancefield group typing kit (Plasmatec, UK) and MALDI-TOF MS (Bruker Daltonik, GmbH, Germany).

**Results**

The distribution of male and female patients was 152 (60.8%) and 98 (39.2%) respectively. The age distribution ranged from 1 to 18 years, with an average age of 6.76 years and a median age of 6 years.

*S. pyogenes* growth was observed in 54 (21.6%) of the 250 samples that were being worked on. Rapid antigen test was positive in 46 (85.2%) of those 54 culture positive cases. The test result was negative in the remaining 8 (14.8%) cases. Moreover, strep-A rapid diagnostic test was positive in 4 cases with negative culture (Table 1). The sensitivity and specificity of the Strep-A rapid diagnostic test in our study were 85.2% and 98%, respectively.

Table 1. Rapid antigen test (RAT) and culture results of throat swab specimens.

	Culture Positive (n)	Culture Negative (n)	Culture Total (n)
RAT Positive (n)	46	4	50
RAT Negative (n)	8	192	200
RAT Total (n)	54	196	250

**Discussion**

Although acute tonsillopharyngitis which is very common especially in children is a self-limited disease, it may cause suppurative and nonsuppurative sequelae when *S. pyogenes* is present. There is no reliable clinical sign or finding to make a definite decision about the etiology of the disease [11].

Acute tonsillopharyngitis is among the most common reasons for inappropriate antibiotic prescribing. It is stated that 70% of the patients who go to the primary care physicians in the USA with a sore throat are prescribed antibiotics and only 20-30% of them have clinical findings suggesting that *S. pyogenes* is the causative agent [12,13].

Rapid antigen detection testing plays an important role in the diagnosis of GAS pharyngitis because of their easy application and quick results. In a study in France, antibiotic prescribing status of doctors who did and did not perform rapid antigen testing in patients with acute tonsillopharyngitis were compared and doctors who did not perform rapid antigen testing showed 20% more antibiotic prescriptions [14]. Sensitivity and specificity of the test may vary according to the factors ranging from the sampling procedure to test kit. In the studies conducted, the specificity of the test is above 95% and the sensitivity is between 65-90% [15,16]. As a result of the studies by Gürol et al., the sensitivity and specificity of the rapid antigen test they used was 64.6% and 96.79%, respectively [17]. The number of patients involved in the study was 132, the sensitivity of the test was 66% and the specificity was 99% [18]. Stewart and his colleagues examined 59 different studies on 55,766 pediatric patients and found the mean sensitivity and specificity of rapid antigen tests as 86% and 92%, respectively [19]. Cohen and his colleagues studied 98 different studies comparing rapid antigen test with throat culture method between 1980 and 2015 [20]. As a result, they found the mean sensitivity of the rapid antigen test as 85.6% and the mean specificity as 95%. Lean and his colleagues evaluated 48 different studies on pediatric patients between 1996 and 2013 for the same purpose and found the sensitivity and specificity of the rapid antigen test as 86% and 96%, respectively [21]. Köse and his colleagues assessed the decision of the pediatrician to arrange antibiotic treatment before and after performing the rapid antigen test for 223 pediatric patients with acute pharyngitis [23]. They also compared the sensitivity and specificity of the rapid antigen test with the culture method. The sensitivity and specificity of the rapid antigen test were found to be 92.1% and 97.3% respectively. The decision of the physicians to prescribe antibiotics after the rapid antigen test was reduced by 53% in the group of patients without *S. pyogenes* in throat culture and increased by 7.9% in the group of patients with *S. pyogenes* in throat culture in case of rapid antigen test. Ruiz Aragon and his colleagues examined 24 different studies in 2009 and found that the sensitivity of the rapid antigen test was 65.6% and the specificity was 96.4% [23].

In our study, the sensitivity of the rapid antigen test was 85.2% and the specificity was 98%, and it was found that our results were compatible with previous studies. Strep-A rapid diagnostic test was positive in 4 cases that had negative culture for *S. pyogenes*. The release of group-A carbohydrate antigen by the bacteria of the *Streptococcus milleri* group in the throat flora and receiving antibiotics shortly before collecting the sample, may be among the reasons for the false positive test result [24,25]. However, in our study, the anamnesis of the patients did not contain any antibiotic use history before the test.

In conclusion, early diagnosis of GAS pharyngitis by rapid antigen testing provides early antibiotic therapy to alleviate symptoms of the patient, prevent sequelae and reduce infectivity. Our study showed that the Orient Gene Strep A rapid test kit is a test that can be used in the diagnosis of acute tonsillopharyngitis because the sensitivity of the kit is within acceptable limits (> 80%). For those patients who have negative results with rapid test, optimal results can be obtained by performing throat culture.

## Scientific Responsibility Statement

*The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.*

## Animal and human rights statement

*All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.*

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## Conflict of interest

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